Hill Wallack LLP
Attorneys at Law

21 Roszel Road
P.O. Box 5226
Princeton, NJ 08543-5226
609.924.0808 *main* | 609.452.1888 *fax*
www.hillwallack.com

July 18, 2019

VIA ECF

Honorable Tonianne J. Bongiovanni, U.S.M.J.
United States District Court for the District of New Jersey
Clarkson S. Fisher Federal Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: ***Sun Pharma Global FZE et al. v. Lupin Limited et al.,***
Civil Action No. 3:18-cv-2213-FLW-TJB (D.N.J.)

Dear Magistrate Judge Bongiovanni:

We, along with Rakoczy Molino Mazzochi Siwik LLP, represent Defendants ("Lupin") in the above-captioned matter. We write in response to Plaintiffs' ("Sun's"):

- July 15, 2019 letter-motion to compel the production of certain post-Complaint emails relating to ANDA Amendments (D.E. 76); and
- letter of today (D.E. 78), in which Sun requested "that the Court hold an expedited telephonic hearing to address the issues set forth in Sun's letter-motions filed on July 8, 2019 (D.E. 71) and July 15, 2019 (D.E. 76)."

In addition, Lupin would like to advise the Court that Lupin has also raised numerous complaints regarding Sun's lack of discovery compliance (*see* Ex. A, July 16, 2019 Letter from Boda to Fish), and although Sun and Lupin are still meeting and conferring, Lupin expects that it will be forced to file its own Motion to Compel in the immediate future. Lupin respectfully requests that the Court address all of the discovery disputes at the same time. Lupin also notes that it can be available to attend a telephonic conference if needed.

I. Sun's Motion to Compel Production of Certain Emails Generated After the Complaint Was Filed Is a Fishing Expedition, and Should be Denied.

Sun's motion to compel the production of post-Complaint emails relating to recent ANDA Amendments should be denied because it is fishing expedition. Lupin has fully complied with its discovery obligations by timely producing its ANDA, all ANDA Amendments, and all FDA correspondence—as well as research and development documents, and emails generated before the litigation commenced. Rather, *Sun's demands* that go well beyond what the Federal and Local Rules contemplate.

A. Lupin Is Not Withholding and/or Concealing Relevant and Responsive Evidence, Sun Seeks Cumulative Evidence, and the Infringement Query Is Properly Based in the ANDA.

As a threshold matter, Lupin has timely produced every amendment and all FDA correspondence relating to its ANDA, and is in full compliance with both the Federal and the District of New Jersey Local Rules. As such, Sun possesses all correspondence sent by FDA, Lupin's responses to FDA, and all information and data underlying Lupin's responses—and Sun has had a majority of these FDA amendments well over a year.[1] In short, Sun has the most up-to-date information about Lupin's proposed product, including its formulation, proposed labeling, and testing results.

Moreover, post-Complaint emails simply *relating* to the FDA amendments are cumulative of the actual FDA correspondence and regulatory filings that have been produced. *See Teva Pharm. USA, Inc. v. Amgen, Inc.*, Civil Action No. 09-5675, 2011 WL 13225286, at *2 (D.N.J. Jan. 24, 2011) (denying motion to compel production of documents related to regulatory filings because they would be "unreasonably cumulative" of the regulatory filing that had already produced).

Furthermore, decades of Hatch-Waxman case law establishes that the infringement analysis "is properly grounded in the ANDA application and the extensive materials typically submitted in its support." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248 (Fed. Cir. 2000). And, "[b]ecause drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry.'" A*lcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1187 (Fed. Cir. 2014) (quoting *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002)).

In addition, Sun has had a full opportunity to question two of Lupin's witnesses about the ANDA and each and every ANDA Amendment, and they did so. And although Sun cites to a number of deposition sections in its letter, it does not point to a single example of where a Lupin witness was unable to answer a single question about Lupin's proposed product based on the absence of any updated emails. In fact, Lupin's witnesses [redacted]

Given these facts, Lupin disagrees with Sun's assertions that it "cannot fully understand or confirm the current and planned composition of Lupin's Proposed Product under the ANDA" and that it could not adequately depose any witnesses. Sun has the final, complete and most up-

[1] The last FDA correspondence is [redacted]

to-date information about Lupin's product as reflected in the ANDA Amendments, and Sun's demand for "related" emails generated after the litigation began is a fishing expedition.

As discussed below, this is further borne out by the specific facts of the case.

1. Lupin's Non-Infringement Defense Is Based on a Viscosity Value Reported in the ANDA Itself.

Asserted Claim 1 of the '999 patent reads as follows:

> 1. A topical ophthalmic composition formulated for application to the eye, said composition comprising a therapeutically effective amount of bromfenac and a flowable crosslinked carboxy-containing polycarbophil mucoadhesive polymer, wherein the composition has a viscosity in the range of about ***1,000 to about 3,400 cps*** and a pH of about 7.4 to about 8.5.

'999 patent at Claim 1 (emphasis added).

As reflected in its Noninfringement Contentions, Lupin's primary Noninfringement defense to Sun's direct infringement allegations is that [redacted] Lupin does not infringe, either literally or under the doctrine of equivalents.

It is undisputed that the [redacted] For example, [redacted]

[redacted]

Further, the post-Complaint emails Sun demands are not relevant to validity. Sun alleges that the "missing Lupin emails likely also contain comments or information regarding objective indicia of non-obviousness." Sun also says the emails may contain "discussions regarding Lupin difficulties in formulation, stability, testing of the composition." Sun, however, is only asserting two objective indicia of non-obviousness: unexpected results and commercial success. Therefore, these speculative difficulties Lupin may have experienced, if any, concerning the formulation, stability, testing of the composition are not relevant to Sun's validity case. Again, Sun appears to be on a fishing expedition.

With respect to Sun's allegation that these documents may contain comments relevant to commercial success, Lupin has confirmed (through 30(b)(6) testimony and supplemental interrogatory responses) that [redacted] that was produced to Sun. Indeed, Sun is *completely speculating* as what they emails at issue might say, and has no credible basis to say that said emails have any relevance to the case—much less that any relevance outweighs the costs and burdens of collection.

And this Court has long recognized that there are limitations on discovery. *Teva*, 2011 WL 13225286, at *1 ("Although the scope of discovery is broad, it is not unlimited; the probative value of the information requested should be balanced against the costs and burdens imposed upon the producing party; discovery shall not be compelled if it 'the discovery sought is

unreasonably cumulative or duplicative' or 'the burden or expense of the proposed discovery outweighs its likely benefit.'" (internal citations omitted)).

Lupin further notes that Sun's demand for production of emails has no cut-off date, and Lupin would unduly burdened by having to continuously collect and produce these internal emails every time it corresponds with FDA; including up and through trial.

B. Lupin's 30(b)(6) Designees Did Not Even Confirm the Emails Exist.

Sun only assumes that there should be emails from Mr. Dahibhate and Mr. Avachat. Lupin has already explained to Sun that the emails that Mr. Dahibhate reviewed while preparing for his deposition were emails that were produced to Sun and emails with Apicore in the emails that were produced. Ex. C, July 2, 2019 Letter from Boda to Fish . That Mr. Dahibhate testified that he "could" have review emails where was the sender appears to be an understandable mistake on Mr. Dahibhate's part since he reviewed the approximately 250 emails with his name in Lupin's production. (And there were also over 200 emails with Mr. Avachat's name in Lupin's production.)

With respect to the document [redacted] Lupin has asked Sun to explain how this document is relevant to the case, but Sun has not yet provided Lupin a response.

II. Sanctions Are Not Warranted as Any Alleged Discovery Misconduct Was Not Intentional and Grounded in Bad Faith.

Lupin's actions do not rise to the level of sanctionable conduct. Rule 37 authorizes the Court to sanction a party for discovery abuses and "assess attorney's fees when it finds that a party has acted in bad faith, vexatiously, wantonly or for oppressive reasons, a party shows bad faith by delaying or disrupting the litigation or by hampering enforcement of a court order, or a fraud has been practiced upon it, or that the very temple of justice has been defiled." G*ivaudan Fragrances Corp. v. Krivda*, Civil Action No. 08-4409 (PGS), 2012 WL 12917268, at *15 (D.N.J. May 8, 2012). In this case, Lupin's actions did not fall into any of these categories, Lupin simply further evaluated the relevance of the emails sought against the burden associated with collecting them, and concluded that Sun's request was unreasonable. Sanctions are not remotely warranted.

Moreover, Sun's assertion that Lupin counsel lied, acted in bad faith, made commitments it had no intention of keeping as part of some grandiose, nefarious scheme to achieve some strategic delay is false and insulting—and also illogical. Rather, Lupin simply wants the case to move forward on the merits, without being encumbered by unwarranted email collection burdens. Furthermore, given that trial is not set to occur until April 2020, any small delay due to discovery disputes can be easily managed.

Furthermore, Lupin's current position is fully in accord with it Reponses to Sun's Requests for Production. Ex. D, Lupin's Responses to Sun's Request For Production Nos. 30-31. For example, in response to Sun's request for "[a]ll documents that refer or relate to any communication with the FDA," Lupin's response was that the request was "overly broad, unduly burdensome" and Lupin stated that it "produced or will produce correspondence ***with the FDA*** related to Lupin's ANDA No. 211239." (*Id.*) (emphasis added). Thus, Sun has long known that Lupin did not consider internal emails regarding FDA correspondence relevant long before it took the depositions of Lupin's 30(b)(6) witnesses. However, during the numerous meet and confers regarding the parties' discovery responses, Sun did not raise this as an issue. If Sun had raised this issue after receiving Lupin's responses—which, as Sun notes was about a year ago—Lupin and Sun could have attempted to resolve this issue. Instead Sun decided to wait until nearly the close of fact discovery to raise the issue with Lupin. That said, during Lupin's search for documents Lupin did collect and produce emails relating to FDA correspondence and FDA Amendments that were dated before the Complaint was filed.

Even if the Court orders that Lupin produce the post-Complaint emails, the Court has the discretion not to award Sun's motion for sanctions. G*ivaudan*, 2012 WL 12917268, at *15. ("[b]ecause of their very potency, inherent powers must be exercised with restraint and discretion"). Rule 37 states that the Court "must not order this payment if . . . (ii) the opposing party's nondisclosure, response, or objection was substantially justified; or (iii) other circumstances make an award of expenses unjust. FED. R. CIV. P. 37(a)(5).

Here, Lupin's objections are substantially justified and considering all the circumstances an award of expenses would be unjust. Importantly, the documents Sun is moving to compel are a subset of documents generated after the complaint was filed, which have only speculative relevance to any issue in the case. Lupin has complied with its discovery obligations, producing documents, and supplementing its production with updated relevant documents when necessary. In fact, before the deposition of Lupin's 30(b)(6) witness, [redacted], Lupin produced updated forecasting documents. In cases where a party has complied with its discovery obligations and only a limited subset documents were not produced, this Court has declined to order sanctions. *See V. Mane Fils S.A. v. Int'l Flavors & Fragrances Inc.*, Civil Action No. 06-2304 (FLW) (D.N.J. Dec. 18, 2008) (ECF 80).

* * *

For all of these reasons, Lupin respectfully requests that Sun's motion to compel production of post-Complaint emails related to certain FDA correspondence be denied, and that all other relief sought by Sun be denied.

III. Sun's Request for an Expedited Telephonic Hearing Should Be Denied.

With regard to Sun's request of today for an expedited telephonic hearing (D.E. 78), Lupin respectfully requests that: (i) Sun's request be denied; and (ii) that the deadline for service of all expert reports be extended by two weeks.

As a threshold matter, because the parties have many open discovery disputes—including numerous complaints that Lupin has raised regarding Sun's lack of discovery compliance (*see* Ex. A, July 16, 2019 Letter from Boda to Fish)—Lupin suggested to Sun on July 16, 2019 that the parties extend the deadline for opening expert reports by two weeks (and also extend the deadline for subsequent rounds of reports). *See* Ex. E, July 16, 2019 Email from Waldron to Morrison and Fish. Sun did not respond to Lupin's suggestion, and instead filed its request for an expedited telephonic hearing, citing the July 31, 2019 expert report deadline as a reason the request was necessary.

The schedule Lupin proposed to Sun is as follows:

Event	Current Date	Proposed Date
Parties to exchange Opening Expert Reports on issues for which party bears the burden of proof	July 31, 2019	August 14, 2019
Parties to exchange Rebuttal Expert Reports	August 28, 2019	September 11, 2019
Defendants to serve Reply Expert Report on Objective Indicia	September 20, 2019	October 4, 2019

See Ex. E, July 16, 2019 Email from Waldron to Morrison and Fish.

Lupin's proposed schedule is a reasonable approach to dealing with the ongoing discovery disputes and the upcoming expert reports, particularly in light of the ample amount of time until dispositive motions (currently due November 15, 2019) and trial (currently set for April 2020).

As such, Lupin respectfully requests that: (i) Sun's request for an expedited hearing be denied; and (ii) that the deadline for service of all expert reports be extended by two weeks.

Thank you for your continued attention to and consideration of this matter.

Respectfully submitted,

/s/ Eric Abraham
ERIC ABRAHAM